UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 01-12257-PBS (Original Central District of California No. 03-CV-2238)
THIS DOCUMENT RELATES TO: State of California, *ex rel.* Ven-A-Care v. Abbott Laboratories, Inc., *et al.* CASE #: 1:03-cv-11226-PBS	Judge Patti B. Saris

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE FIRST AMENDED COMPLAINT-IN-INTERVENTION

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Defendants submit this memorandum of law in support of their motion to dismiss Plaintiffs' First Amended Complaint-In-Intervention.[1]

Under the California False Claims Act, the State of California ("California") and Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") allege that Defendants caused "false or inflated" drug pricing information to be published by third-party pricing compendia, which was used by California in determining Medicaid reimbursement paid to healthcare providers (largely pharmacies and physicians) for dispensing and/or administering Defendants' drugs. As a result, according to Plaintiffs, California Medicaid (referred to as "Medi-Cal") overpaid providers.

These allegations are flatly contradicted by the plain language of Medi-Cal statutes and regulations, as well as by California's supplemental drug rebate program, under which it has received significant price rebates directly from Defendants. Plaintiffs' allegations are also belied by the public record, which plainly shows that California waited until 2002 to even make minimal changes to its approach to Medicaid payments -- despite the fact that a 1996 audit confirmed that Medi-Cal was reimbursing providers at rates well in excess of the providers' acquisition costs and that this lawsuit was filed in 1998.

In 1996, the United States Department of Health and Human Services Office of Inspector General ("HHS-OIG") audited pharmacy acquisition costs for drugs reimbursed by Medi-Cal, and stated that California pharmacies were purchasing drugs at substantial discounts off Average Wholesale Price ("AWP"). *See* DEP'T OF HEALTH & HUMAN SERV. OFFICE OF INSPECTOR GEN.,

[1]This Memorandum of Law is submitted on behalf of Abbott Laboratories Inc.; Armour Pharmaceutical Co.; Aventis Pharmaceuticals Inc. (Hoechst Marion Roussel, Inc., a predecessor of Aventis Pharmaceuticals Inc., is no longer a separate legal entity and therefore is not a proper defendant); B. Braun Medical Inc.; Baxter Healthcare Corp.; Ben Venue Laboratories, Inc. (note that Bedford Laboratories is a division of Ben Venue Laboratories, Inc., not a separate legal entity, and therefore is not a proper defendant); Boehringer Ingelheim Corp.; Bristol-Myers Squibb Company; Dey, Inc.; Dey, L.P.; Immunex Corp.; Mylan Laboratories Inc.; Mylan Pharmaceuticals Inc.; Roxane Laboratories, Inc.; Sandoz Inc.; Schering-Plough Corp.; Warrick Pharmaceuticals Corp.; and ZLB Behring LLC (f/k/a Aventis Behring LLC).

REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE CALIFORNIA DEPARTMENT OF HEALTH SERVICES (May 31, 1996) (Ex. A). In response, the California Department of Health Services acknowledged that the 1996 audit:

> indicates that a reduction in our drug ingredient cost reimbursement would be appropriate at this time. DHS intends to use these results, when published in the final report, to support a provision of our Governor's budget proposal to decrease drug ingredient reimbursement. *The audit results will, hopefully, substantiate DHS' position that current drug ingredient reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies.*

1996 HHS-OIG Report Appendix 4 at 1 (emphasis added) (Ex. A).

The California political process, however, apparently did not work out to the liking of the Attorney General's office. As a result, what in 1996 was viewed by California state officials as a political question needing a political solution, is now being prosecuted as "fraud."

As explained below, the First Amended Complaint-In-Intervention should be dismissed (i) under Fed. R. Civ. P. 9(b) because it fails to plead the circumstances of fraud with particularity; and (ii) under Fed. R. Civ. P. 12(b)(6) because it fails to state a claim under the California False Claims Act.

BACKGROUND

I. PROCEDURAL HISTORY

Ven-A-Care initiated this action in July 1998 by filing a complaint under seal in California Superior Court, pursuant to the *qui tam* provisions of the California False Claims Act ("CFCA"). *See* CAL. GOV'T. CODE § 12652(c). The CFCA's *qui tam* provisions allow private parties, called "relators," to file suit alleging fraud against the State of California. While a *qui tam* complaint is under seal, the California Attorney General is required to investigate the

allegations and decide whether to intervene. *Id.* If the Attorney General intervenes, then the State takes over the litigation and the relator is entitled to 15-33 percent of any eventual recovery. *See id.* § 12652(g)(2). If the Attorney General declines to intervene, the relator may litigate the case and is entitled to receive 25-50 percent of any eventual recovery. *See id.* § 12652(g)(3).

On August 13, 2002, while the action was still under seal, Ven-A-Care filed an amended complaint. Ven-A-Care's amended complaint alleged that pharmaceutical companies caused Medi-Cal to overpay for drugs, and also contained allegations relating to the federal Medicaid drug rebate program.

On January 3, 2003, the Attorney General filed a notice of partial intervention against three defendants, Abbott Laboratories ("Abbott") and Wyeth, Inc. and one of its corporate affiliates (collectively, "Wyeth"). The Attorney General subsequently served Abbott and Wyeth with a Complaint-in-Intervention. The Attorney General requested and received more time to decide whether to intervene on the federal Medicaid drug rebate claims.

Thereafter, Abbott and Wyeth removed the action to the United States District Court for the Central District of California. The federal drug rebate allegations formed the basis of federal jurisdiction. Plaintiffs moved for remand. In June 2003, while that motion was pending, the Judicial Panel on Multidistrict Litigation transferred the action to this Court as part of MDL 1456. On September 18, 2003, this Court denied the motion for remand and advised California that it had six months to decide whether to intervene on the still-sealed portions of the complaint.

After prompting from this Court, on August 25, 2005, Plaintiffs filed the First Amended Complaint-In-Intervention (the "Amended Complaint"), which is the subject of this motion to dismiss. The Amended Complaint names thirty-nine defendants.

II. THE AMENDED COMPLAINT

Plaintiffs assert five counts in their Amended Complaint:

- Count I alleges that the Defendants knowingly caused providers to submit false claims to Medi-Cal, in violation of Cal. Gov't Code Section 12651(a)(1). *See* Amended Complaint ("Compl.") ¶ 182;

- Count II alleges that Defendants knowingly caused false records or statements to be used by Medi-Cal to pay false claims submitted by providers, in violation of Cal. Gov't Code Section 12651(a)(2). *See id.* ¶ 185;

- Count III alleges that Defendants were beneficiaries of submissions of false claims to Medi-Cal, subsequently discovered the falsity of the claims, yet failed to disclose the false claims to California within a reasonable time, in violation of Cal. Gov't Code Section 12651(a)(8). *See id.* ¶ 188;

- Count IV alleges that Defendants violated the California anti-kickback statute (Cal. Wel. & Inst. Code Section 14107.2), which, in turn, caused providers to submit false claims, in violation of Cal. Gov't Code Section 12651(a)(1). *See id.* ¶ 19; and

- Count V alleges that Defendants violated the California anti-kickback statute (Cal. Wel. & Inst. Code Section 14107.2), which, in turn, caused false records or false statements to be used by Medi-Cal to pay false claims submitted by providers, in violation of Cal. Gov't Code Section 12651(a)(2). *See id.* ¶ 200.

The Amended Complaint alleges almost nothing about the claims actually submitted to Medi-Cal by healthcare providers. It does not allege the supposed false content of the claims. It alleges instead that "Defendants reported or caused to be reported false or misleading prices to Medi-Cal by reporting false or misleading price information . . . to [pricing compendia] with knowledge that [the pricing compendia] in turn would utilize such false and misleading price information in determining the AWPs and DPs [Direct Prices] that were reported to Medi-Cal." Compl. ¶ 36. Plaintiffs allege that the "false or misleading prices" that Defendants reported to pricing compendia "include[d] but [were] not necessarily limited to AWP, Suggested Wholesale Price ("SWP"), CDP, WAC, DP, List Price and direct wholesale price." *Id.* Plaintiffs further allege that California was injured by Defendants' conduct because Medi-Cal relied on First

DataBank ("FDB"), a pricing compendium, "as its primary source of pricing data and has utilized reports of AWP, DP and FUL supplied by FDB (which FULs are obtained from CMS) in setting providers' reimbursement amounts for Defendants' prescription drugs." *Id.* ¶ 35(c).

Plaintiffs' allegations regarding Defendants' supposed violations of California's anti-kickback statute, the predicate for the CFCA allegations in Counts IV and V, are unclear. They allege that Defendants offered or paid "remuneration to their customers in the form of price reductions and/or illegal remuneration from Medi-Cal to induce them to purchase" their drugs. Compl. ¶¶ 191 and 197.

Plaintiffs seek treble damages and civil penalties of $10,000 for each allegedly false claim submitted to Medi-Cal for the time period of January 1994 to the present.

III. THE MEDI-CAL PROGRAM

A. Overview.

Medi-Cal is the California version of Medicaid, a joint federal-state health benefits program for the poor. California administers Medi-Cal through two systems: (1) fee-for-service; and (2) managed care. *See* CAL. WEL. & INST. CODE § 14016.5. Under the traditional, fee-for-service program, California reimburses providers a certain amount for each service they perform. In an attempt to control Medi-Cal expenditures, California requires certain Medi-Cal beneficiaries to enroll in a managed care program. *See* CAL. WEL. & INST. CODE § 14200 *et seq*. California contracts with private third parties to administer these managed care plans. These third-party managed care plans establish their own drug formulary and set their own drug reimbursement formula. *Id.* Accordingly, the allegations in Plaintiffs' Amended Complaint can apply only to the fee-for-service program.

The federal Medicaid program requires state Medicaid programs, like Medi-Cal, that choose to provide a prescription drug benefit to its beneficiaries, to reimburse providers for

prescription drugs at the lower of the estimated acquisition cost ("EAC"), usual and customary charges, or Federal Upper Limit ("FUL"). According to federal regulation, EAC is supposed to be a state's best estimate of providers' acquisition cost of the drugs. *See* 42 C.F.R. § 447.301. Federal law also requires state Medicaid programs to set reimbursement rates at such a level to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." *See* 42 U.S.C. § 1396a(a)(30)(A).

B. Medi-Cal's Drug Reimbursement Scheme.

For most categories of drugs, Medi-Cal is required by California law to reimburse providers at the lowest of (1) EAC; (2) Federal Allowable Cost ("FAC"), which is the FUL established by CMS; (3) Maximum Allowable Ingredient Cost ("MAIC"); or (4) the amount charged by the provider. *See* Compl. ¶ 27; CAL. WEL. & INST. CODE § 14105.45. In certain instances, as Plaintiffs admit, Medi-Cal reimbursed providers based on the providers' invoice cost. *See* Compl. ¶ 29.

According to Plaintiffs, California sets EAC as the Direct Price published by First DataBank or the AWP published by First DataBank, minus a certain percentage. *See* Compl. ¶¶ 27 and 35. MAIC is a price set by California for certain multiple-source (generic) drugs; currently, it is based "on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by [California's Department of Health Services]." *See* CAL. WEL. & INST. CODE § 14105.45(a)(12).

C. Rebates Paid By Drug Manufacturers To Medi-Cal.

California's net expenditure for Medicaid reimbursement of prescription drugs is lowered by two types of rebates it receives from drug manufacturers. First, California receives rebates through the federal Medicaid rebate program. In order for a manufacturer's drugs to be reimbursed under a state's Medicaid program, federal law requires manufacturers to enter a contract to pay rebates to the states for each drug for which the state Medicaid program pays providers.[2] *See* 42 U.S.C. § 1396r-8(a)(1), (b)(2) & (3).

In addition, California receives supplemental rebates for which it has negotiated directly with drug manufacturers. This rebate is in addition to the rebate California receives from manufacturers through the federal rebate program. California's supplemental rebate program has been in effect since 1990. *See* CAL. WEL. & INST. CODE § 14105.33. California secures drug manufacturer participation in this program by requiring drug manufacturers to negotiate a supplemental rebate contract to have its drugs included on the Medi-Cal formulary. *See* CAL. WEL. & INST. CODE §§ 14105.33, 14105.35 and 14105.37. California's supplemental rebate program initially targeted innovator single-source drugs, but it was later expanded to include multiple-source drugs as well. *See* CAL. WEL. & INST. CODE § 14105.3(d) ("The department shall contract with manufacturers of single-source drugs on a negotiated basis, and with manufacturers of multisource drugs on a bid or negotiated basis.").[3]

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[2] This Court has previously described the federal Medicaid rebate program. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 195-97 (D. Mass. 2004).

[3] California's supplemental rebate contracts with manufacturers are usually based on the manufacturer's "best price." *See* CAL. WEL. & INST. CODE § 14105.33. The California rebate statute defines "best price" as "the negotiated price, or the manufacturer's lowest price available to any class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities within the United States, that contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits…." CAL. WEL. & INST. CODE § 14105.31(b).

Thus, for the last fifteen years, California has negotiated with drug manufacturers to obtain rebates to defray the cost of what Medi-Cal pays providers. These rebates are significant. In fiscal year 1999-2000, California received $483 million in federal rebates and $158 million in state supplemental rebates, equal to 37 percent of Medi-Cal's total fee-for-service pharmacy expenditures. *See* MEDI-CAL POLICY INSTITUTE, THE MEDI-CAL PHARMACY BENEFIT (July 2002) (Ex. B). In fiscal year 2003-2004, California received nearly $1.5 billion in drug rebates, including $481 million through its state supplemental rebate program. *See* CALIFORNIA HEALTH CARE FOUNDATION, THE MEDICARE DRUG BENEFIT: IMPLICATIONS FOR CALIFORNIA 7 (April 2005) (Ex. C).

IV. CALIFORNIA HAS LONG PUBLICLY RECOGNIZED THAT ITS EAC OFTEN EXCEEDED THE PRICE AT WHICH PROVIDERS PURCHASE DRUGS MANUFACTURED BY DEFENDANTS

The regulatory history of Medicaid makes clear that California has recognized publicly, for many years, that Medi-Cal uses an EAC that typically exceeds the price at which providers can purchase Defendants' drugs. Despite this knowledge, California did not change its reimbursement methodology until September 2002, because of political reasons and to ensure that providers participate in the Medi-Cal program. *See infra* at 18-19. Thus, it is unsurprising that nowhere in the Amended Complaint do Plaintiffs allege that California did not know that AWP and Direct Price often substantially exceed the price at which providers can typically purchase drugs.

More specifically, California's MAIC program, which caps the maximum amount that Medi-Cal will reimburse for most generic drugs, has been in effect since at least the mid-1970's. *See* Memorandum from Richard Ochener to Jay A. Gould, *Preliminary Legal Review of Proposed Title 22 Regulation Amendments to Comply with MAC/EAC* (July 22, 1976) (describing the procedure for integrating the federal Maximum Allowable Cost program into

California's existing MAIC program) (Ex. D).[4] Further, the regulatory record reveals that in 1987-1988, Medi-Cal had lists comparing the published prices of drugs to their actual cost. *See* excerpts of price lists found in CAL. CODE REGS. tit. 22, § 51512 (2005), DHS No. R-84-87, Reg. 88, No. 14 (1988) (Ex. E).[5] These price lists show that California knew that AWP and Direct Price are often significantly higher than the actual sale price of the drug.[6]

In 1996, Medi-Cal acknowledged to the federal government, in response to an HHS-OIG audit, that Medi-Cal knowingly pays more for drugs than what providers themselves pay for the drugs. *See* 1996 HHS-OIG Audit (Ex. A). The HHS-OIG conducted its audit "to develop an estimate of the difference between the actual acquisition cost of drugs of the pharmacies and AWP for both brand name and generic drugs." *See* Cover Letter to 1996 HHS-OIG Audit at 1 (Ex. A). At the time, Medi-Cal calculated EAC as AWP-5% or Direct Price. This HHS-OIG audit, conducted almost ten years ago, documented that, in California, "pharmacy purchase invoice prices" for generic drugs were, on average, approximately 41% below AWP and for brand name drugs were, on average, approximately 17.5% below AWP. *Id.* (Ex. A)

In response, John Rodriguez, Deputy Director of California's Department of Health Services ("DHS") Medical Care Services, stated that the HHS-OIG audit "indicates that a reduction in our drug ingredient cost reimbursement would be appropriate at this time." *See* HHS-OIG Audit Appendix 4 at 1 (Ex. A). In addition, DHS stated that it intended to "use these results [of the audit] . . . to support a provision of our Governor's budget proposal to decrease

[4] This Court has previously recognized that it may take judicial notice of public records on a Rule 12(b)(6) motion. *See In re Vertex Pharm., Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) (Saris, J.).

[5] DHS' record from this time frame contains hundreds of pages of price lists. These lists contain pricing information for many of the defendants' drugs named in the Amended Complaint. To keep the amount of paper submitted to the Court to a minimum, we have attached only the first ten pages of two of the price lists. At the Court's request, we can provide additional price lists from DHS' record.

[6] California used this data to justify expansion of cost limitations on generic drugs in response to testimony in opposition to changes to a Medi-Cal regulation concerning reimbursement. *See* R-84-87, Statement of Reasons (Ex. F).

drug ingredient reimbursement. The audit results will, hopefully, substantiate DHS's position that current drug ingredient reimbursement by the Medi-Cal program does not reflect actual purchasing activity of California pharmacies." *Id*. (Ex. A). Despite this information, California took no steps to reduce its reimbursement to providers.

Moreover, in July 1998, when it originally filed its complaint under seal, Ven-A-Care provided California with its actual acquisition prices for drugs. *See* Compl. ¶ 3. Thus, California was, once again, given notice that its current reimbursement practices resulted in a "spread" to California providers. Yet, California still took no action to change its EAC.

Although armed for years with the knowledge that Medi-Cal was supposedly over-reimbursing providers for ingredient cost, California did not lower its reimbursement rates until September 30, 2002. Even then, it only reduced EAC from AWP-5% to AWP-10% -- an amount which still resulted in a reimbursement rate far in excess of the prices that the 1996 HHS-OIG audit showed providers could acquire some drugs. The 2002 amendments also eliminated reimbursement based on Direct Price and redefined EAC as the lower of Average Sales Price ("ASP") or AWP-10%. CAL. WEL. & INST. CODE § 14105.46(b) (2003). ASP was defined "as the price reported to the department as required by agreements between the State of California and the manufacturer." CAL. WEL. & INST. CODE § 14105.46(a)(5) (2003). The "agreements" to which this regulation refers are the California specific supplemental rebate contracts with manufacturers, discussed above. Less than two years later, on August 16, 2004, California repealed Cal. Wel. & Inst. Code Section 14105.46 and replaced it with Cal. Wel. & Inst. Code Section 14105.45, which, again, stated that Direct Price cannot be used to establish the EAC and established EAC as the lower of AWP-17 %, "the selling price," FUL or MAIC. *See* CAL. WEL. & INST. CODE § 14105.45(b)(2). "Selling price" is defined as "the price used in the

establishment of the estimated acquisition cost. The department shall base the selling price on average sales price. . . ." CAL. WEL. & INST. CODE § 14105.45(a)(12).[7]

In sum, like so many other states, California has long known that it reimbursed providers substantially more than what the providers paid to acquire Defendants' drugs. And, like other states, California did so as a result of political factors or to ensure adequate provider participation in Medi-Cal. *See* HHS DEP'T OF HEALTH & HUMAN SERV. OFFICE OF INSPECTOR GEN., STATE STRATEGIES TO CONTAIN MEDICAID DRUG COSTS 10-11 (October 2003) (discussing pharmacy opposition to reimbursement reductions and the need to ensure adequate provider participation in Medicaid programs) (Ex. G). Knowing full well that it was paying a "spread" to providers, California pursued supplemental rebates from drug companies to defray the costs of Medi-Cal drug coverage. Given this history, California now overreaches in bringing this action.

ARGUMENT

I. THE AMENDED COMPLAINT SHOULD BE DISMISSED FOR FAILURE TO COMPLY WITH RULE 9(b)

Plaintiffs' Amended Complaint fails to plead the "circumstances of fraud" with particularity as required by Rule 9(b).[8] *See* FED. R. CIV. P. 9(b). In the False Claims Act ("FCA") context, Rule 9(b) requires not only that the underlying fraudulent scheme be pled with particularity, but also that allegations relating to the actual false claims submitted to the government -- "that constitute the essential element of an FCA qui tam action" -- must be pled with particularity. *See United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220,

[7] Section 14105.45 also redefined "average sales price." *See* CAL. WEL. & INST. CODE § 14105.45(a)(1); discussion *infra* at 19.

[8] In a multi-defendant case, the Amended Complaint should be reviewed for sufficiency as to each defendant separately. Even if a complaint satisfies Rule 9(b) as to some defendants, the complaint should still be dismissed as to those defendants against whom the circumstances of fraud were not pled with particularity. *See Vicom, Inc. v. Harbridge Merchant Servs.*, 20 F.3d 771, 778 (7th Cir. 1994); *Rhone v. Energy North, Inc.*, 790 F. Supp. 353, 361 (D. Mass. 1991).

232 (1st Cir. 2004) (affirming dismissal of FCA claims for failure to comply with Rule 9(b)). "Liability under the False Claims Act arises from the submission of a fraudulent claim to the government, not to the disregard of government regulations or failure to maintain proper internal policies." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005) (affirming dismissal of FCA claim for failure to plead with particularity, where plaintiff "provided the 'who,' 'what,' 'when,' and 'how' of improper practices, but failed to allege the 'who,' what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government."). Rule 9(b) requires more than conclusory statements that false claims were submitted to the government as a result of fraudulent activity. *United States ex. rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (affirming dismissal of complaint on Rule 9(b) grounds where plaintiff, despite making detailed allegations about fraudulent schemes, did not identify any dates or amounts of claims and no copy of a single claim or payment was provided).

Here, in contravention of Rule 9(b), Plaintiffs have alleged nothing about the alleged false claims, nor the identities of the providers who submitted them, their supposed false content, or any other fact. In *Karvelas*, this Circuit described how plaintiffs can satisfy Rule 9(b) when describing the alleged false claims:

> As applied to the FCA, Rule 9(b)'s requirement that averments of fraud be stated with particularity - specifying the 'time, place, and content' of the alleged false or fraudulent representations, means that a relator *must provide details that identify particular false claims for payment that were submitted to the government.* In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity.

Karvelas, 360 F.3d at 232-233 (emphasis added). While the characteristics about the claims set forth above "do not constitute a checklist of mandatory requirements…, some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b)." *Id.* at 233 (citations omitted). Plaintiffs have failed to satisfy the *Karvelas* test for pleading a False Claims Act case under Rule 9(b). Because Plaintiffs have not alleged with sufficient particularity a single *false claim* submitted to California, all five Counts of the Amended Complaint (Counts I-V) should be dismissed.

Plaintiffs further fail to comply with Rule 9(b) in Counts II and V by failing to sufficiently describe the "false records or statement[s]" by Defendants that are required for a violation of Cal. Gov't. Code Section 12651(a)(2). Plaintiffs do not allege with particularity the pricing information submitted by Defendants, when the information was submitted, by whom, to whom, or what was false about any such information. Instead, Plaintiffs sweepingly allege that Defendants provided "false or misleading price information including but not necessarily limited to AWP, Suggested Wholesale Price ("SWP"), CDP, WAC, DP, List Price and direct wholesale price" to pricing compendia. Compl. ¶ 36. Simply listing a string of possible pricing terms that Defendants may have submitted to pricing compendia does not satisfy Plaintiffs' Rule 9(b) obligations.

The exhibits attached to the Amended Complaint (which list some published AWPs and Direct Prices reported by pricing compendia), do not remedy Plaintiffs' Rule 9(b) defects. According to Plaintiffs, the actionable statements in Counts II and V are Defendants' statements *to* the pricing compendia, not the prices published *by* the compendia. Nowhere in the Amended Complaint do Plaintiffs state with particularity the pricing information allegedly sent by Defendants to the pricing compendia, much less what was false about that information.

Counts IV and V suffer additional and independently dispositive pleading deficiencies. In Counts IV and V, Plaintiffs allege that providers' claims were false because Defendants violated California's anti-kickback statute, Cal. Wel. & Inst. Code Section 14107.2. Plaintiffs do not plead with particularity any facts or circumstances constituting a single violation of that statute by any Defendant. Plaintiffs allege that Defendants knowingly offered or paid remuneration to providers in the form of price reductions and/or in the form of illegal remuneration from Medi-Cal to induce providers to purchase Defendants' drugs. *See* Compl. ¶¶ 191 and 197. Plaintiffs do not describe, however, when, where, or how this illegal remuneration was paid to providers. Nor do they allege how Defendants' alleged violation of this statute caused providers' claims to be false.

Plaintiffs' multiple pleading failures warrant dismissal of the Amended Complaint under Rule 9(b).

II. ALL COUNTS IN THE AMENDED COMPLAINT SHOULD BE DISMISSED PURSUANT TO RULE 12(b)(6)

The Amended Complaint should also be dismissed pursuant to Rule 12(b)(6) because it fails to state a claim upon which relief may be granted. While Plaintiffs have alluded to a fraudulent scheme by Defendants, these generalized allegations do not give rise to a cause of action under the CFCA -- the vehicle through which California is trying to recover Medi-Cal "overpayments" to providers. Specifically, Plaintiffs' Amended Complaint should be dismissed under Rule 12(b)(6) for at least the following reasons:

- Plaintiffs have not alleged falsity;
- Plaintiffs have not alleged that Defendants presented or caused to be presented a false claim;
- Defendants are not "beneficiaries," nor did they "discover" any false claims;

- Plaintiffs do not allege facts sufficient to constitute a violation of California's anti-kickback statute and, alternatively, California's anti-kickback statute is preempted by federal law; and

- Plaintiffs fail to state a claim for drugs that were reimbursed on MAIC or any basis other than AWP or Direct Price.

A. All Counts In The Amended Complaint Should Be Dismissed Because Plaintiffs Have Not Alleged Falsity.

Falsity is an essential element of the CFCA. There are three independent ways in which Plaintiffs have failed to satisfy the falsity element. First, Plaintiffs have not alleged the submission of a "false claim." Second, Plaintiffs cannot allege that the terms Direct Price and AWP -- the predicate for each of Plaintiffs' claims -- are false. Third, California's knowledge of the facts surrounding the claims and California's continued acquiescence in approving and paying allegedly "false" claims precludes a good faith allegation of falsity under CFCA precedent.

1. All Counts in the Amended Complaint should be dismissed because the Amended Complaint fails to allege the submission of a "false claim."

The submission of a "false claim" is an element of each of the five CFCA counts. *See* CAL. GOV'T. CODE § 12651(a)(1) ("Knowingly presents or causes to be presented…a *false claim* for payment or approval") (Counts I and IV); CAL. GOV'T. CODE § 12651(a)(2) ("Knowingly makes, uses, or causes to be made or used a false record or statement to get a *false claim* paid or approved….") (Counts II and V); CAL. GOV'T. CODE § 12651(a)(8) ("Is a beneficiary of an inadvertent submission of a *false claim*…, subsequently discovers the falsity of the claim, and fails to disclose the *false claim*…after discovery of the *false claim*.") (Count III).

Consequently, to state a claim under any of the five counts, *inter alia*, Plaintiffs must allege that a "false claim" was submitted to Medi-Cal. *See Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 864 (2001) (affirming trial court's granting of California

Attorney General's motion to dismiss FCA action). Because the CFCA focuses on "claims," CFCA liability attaches "not to underlying fraudulent [or wrongful] activity . . . , but to the claim for payment."[9] *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (explaining that the FCA is designed for false invoice submissions directly to governments); *see also United States ex rel. Local 342 Plumbers & Steamfitters v. Caputo Co.*, 321 F.3d 926, 933 (9th Cir. 2003) ("For a false claim suit to succeed, the plaintiff must show that the claim was false, that is, contrary to an existing state of things."); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) (en banc) ("There is no liability under [the False Claims Act] for a false statement unless it is used to get a *false claim* paid.") (emphasis added); *United States ex rel. Hopper v. Anton*, 91 F.3d. 1261, 1265-66 (9th Cir. 1996) (stating that the FCA requires a false claim and explaining that "[t]his does not mean that other types of violations of regulations, or contracts, or conditions set for the receipt of moneys, or of other federal laws and regulations are not remediable; it merely means that such are not remediable under the FCA or the citizen's suit provisions contained therein").

According to the Amended Complaint, the "false" claims that form the basis of Plaintiffs' allegations are the claims submitted by providers to Medi-Cal for reimbursement:

> The claims which are the subject of this action were submitted to Medi-Cal for reimbursement for prescription drugs provided to Medi-Cal beneficiaries. Claims for each prescription are submitted on hard copy claim forms or through an electronic claim filing procedure using drug identification numbers known as National Drug Code ("NDC") numbers. Claims for physicians' services are submitted and paid using California-specific "X-Codes."

Compl. ¶ 37.

[9] Cases interpreting the federal False Claims Act ("FCA") provide guidance for interpreting the CFCA. "The [California] False Claims Act was enacted in 1987 and is patterned largely on similar federal legislation." *Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 858 (2001).

The published AWPs or Direct Prices for Defendants' drugs are not part of the claim form, nor is any of the allegedly "false" pricing information that Plaintiffs allege Defendants reported to the pricing compendia. Rather, the Medi-Cal claim forms, as described by Plaintiffs' Amended Complaint, contain information reported by providers -- such as the provider's billed charges for dispensing and/or administering the drug. Providers are given discretion in setting their charges on these forms under California law. There are no statutes or regulations that require providers to charge only their actual acquisition costs for drugs. Providers are free to set their charges at a rate higher than their purchase price.[10] Yet, importantly, there is no allegation in the Amended Complaint that the claim forms submitted by the providers -- the claims that are the alleged "false claims" under the CFCA -- are false. There is no allegations that providers' billed charges contained on the forms are false in any way, nor is there any allegation that any other information on the claim forms is false.

After the claim is submitted by the provider and received by the State, Medi-Cal then calculates the provider's reimbursement as the lower of: (i) the provider's charges as contained in the Medi-Cal claim form; (ii) EAC, which Medi-Cal calculated as either Direct Price or a percentage of AWP (as obtained from third party pricing compendia); (iii) FUL; or (iv) MAIC. *See* Compl. ¶ 26. The fact that Medi-Cal may use AWP and/or Direct Price in determining an upper bound for provider reimbursement has nothing to do with whether the providers' claim forms -- the alleged CFCA "false claims" -- are false. *See People v. Duz-Mor Diagnostic Lab., Inc.*, 68 Cal. App. 4th 654, 672-673 (1998) (finding there could be no false claim where claim was submitted in accordance with government directions).

[10] By contrast, the California legislature has chosen to limit how much a provider can charge Medi-Cal for certain other items, such as purchased laboratory tests. *See* CAL. BUS. & PROF. CODE § 655.5 (requiring that a physician charge Medi-Cal and other third party payors exactly what the lab charged the physician).

Because Plaintiffs have not alleged that the providers' claims are false, there can be no violation of the CFCA. All five Counts of Plaintiffs' Amended Complaint should therefore be dismissed.

2. All Counts in the Amended Complaint should be dismissed because Plaintiffs cannot allege that "AWP" and "Direct Price" are false.

Each Count of the Amended Complaint is predicated on the alleged falsity of AWP and Direct Price. Because California defines AWP and Direct Price as whatever is listed in the pricing compendia, these terms cannot be false. To the extent Plaintiffs claim that, despite the statutory definition, AWP and Direct Price should have approximated actual sales price, their claims nevertheless fail because those terms are too uncertain.

From the 1970's to 2002, California regulations required Medi-Cal to calculate EAC for a given drug using the Direct Price and AWP for that drug as "listed . . . in the Department's primary reference source." *See* 22 C.C.R. §§ 51513 & 51513.5 (2003). For those products not listed in the Department's primary reference source, the regulations required Medi-Cal to use the price "listed . . . in the secondary price reference source" or (if not listed in the secondary source) the price "[listed] in the principal labeler's catalogue." *Id*. In September 2002, as part of a legislative overhaul of provisions relating to Medi-Cal, California confirmed its long-standing practice of defining AWP and Direct Price to mean the prices reported by the pricing compendia. *See* CAL. WEL. & INST. CODE § 14105.46 (2003) (repealed August 16, 2004, and definitions incorporated into CAL. WEL. & INST. CODE § 14105.45). Significantly, unlike the terms "best price" and "average sales price," California did not define AWP and Direct Price with reference to economic or transactional benchmarks. *Compare* CAL. WEL. & INST. CODE §§ 14105.31(b) & 14105.6(a)(5) *with* CAL. WEL. & INST. CODE §§ 14105.45(a)(2) & 14105.45(a)(3).

California defines "best price" as the "negotiated price" between drug manufacturers and California or the contract price to customers, inclusive of all cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits. *See* CAL. WEL. & INST. CODE § 14105.31(b). California defines "average sales price" as "the sales price for a [NDC] for a calendar quarter for a manufacturer for a unit" calculated as the manufacturer's sales to all purchasers in the calendar quarter, divided by the total number of units sold. CAL. WEL. & INST. CODE § 14105.45(a)(1). The statute defining "average sales price" further provides that: "In calculating the manufacturer's average sales price, the price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates . . . ." *Id.* 14105.45(a)(1)(C).

By contrast, Cal. Wel. & Inst. Code Section 14105.45(a)(2) defines "Average Wholesale Price" as "the price for a drug product listed in the department's primary price reference source." Likewise, Cal. Wel. & Inst. Code Section 14105.45(a)(3) defines "Direct Price" as "the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source." Based on the California's statutory definitions, an AWP or Direct Price listed in the pricing compendia (the department's primary reference source) could never be "false" as a matter of law because AWP and Direct Price are defined as what is listed in the pricing compendia.

California does not (and cannot) point to any relevant authority that defines "Direct Price" and/or "AWP" as providers' actual acquisition cost, net any discounts, rebates, etc., and therefore cannot establish the falsity of the terms. Indeed, actual acquisition cost, net any discounts rebates, etc., is the very definition that the California legislature assigned to "average sales prices" -- not AWP or Direct Price. *See* CAL. WEL & INST. CODE § 14105.45(a)(1). By

defining AWP and Direct Price in a different manner than "average sales price," the California legislature clearly intended the terms to have different meanings.[11]

If California now wants to deviate from its statutory definitions and claim that AWP and Direct Price mean something other than what is published in the pricing compendia, these terms are too uncertain to allow prosecution under the CFCA. *See Duz-Mor Diagnostic Labs.*, 68 Cal.App.4th 654 (affirming that there was no California False Claims Act violation where "the manuals and regulations which govern Medi-Cal billing are technical and complex, and are subject to different interpretations, even by representatives of Medi-Cal"); *see also United States ex rel. Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1049 & n.9 (N.D. Ill. 1998) (granting summary judgment for defendant and holding that government has burden to prove that ambiguous terms at issue are not subject to any other reasonable interpretation), *aff'd*, 183 F.3d 730 (7th Cir. 1999).

The absence of "falsity" for a false claims act claim where regulatory terms are not sufficiently certain is confirmed by two analogous federal cases that were dismissed pursuant to Rule 12(b)(6): *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998) and *United States ex rel. Gathings v. Bruno's, Inc.*, 54 F. Supp. 2d 1252, 1259-60 (M.D. Ala. 1999). In *Cox*, plaintiffs alleged that defendants submitted false claims for air ambulance mileage reimbursement because they used "statute miles" rather than "nautical miles." The court found that the relator had failed to state a claim under the False Claims Act, because the relator

[11] Additionally, if AWP and Direct Price were actual net prices many providers would be reimbursed less than what the drug actually cost them to acquire, since Medi-Cal reimbursement methodology discounts AWP. If that were the case, many providers would not participate in Medi-Cal. That could not possibly have been Medi-Cal's intent in using AWP and Direct Price as a basis for reimbursement. On the contrary, the legislative and regulatory history of the Medi-Cal program demonstrate that California intended for providers to make a profit on the drugs they dispensed to encourage them to stay in the Medi-Cal program. *See* discussion *supra* at 8-11.

could not point to any "law, regulation, or other source" that required defendants to submit their claims in "nautical miles":

> [Relator] does not identify any law, regulation, or other source suggesting federal medical programs expected air ambulance mileage claims to be in nautical miles rather than statute miles. In fact, relator describes the conversion practice in his complaint as "the standard, but carefully concealed, practice in the industry." *A standard billing practice within an industry could hardly be said to be false, when no controlling authority requires parties to submit claims in nautical rather than statute miles.*

Cox, 29 F. Supp. 2d at 1026 (citation omitted; emphasis added). In other words, absent an unambiguous and sole meaning of the term "miles," converting "nautical miles" to "statute miles" and submitting reimbursement for "statute miles" was not a false statement. *Id.*; *see also United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 100 (D. Mass. 2001) (Saris, J.) (granting summary judgment for defendant in False Claims Act action and stating that "[Plaintiff] has not alleged a crucial element of this claim, which is that the statement by Defendants is false" where plaintiffs could not rebut defendant's interpretation of a disputed term).

In *Gathings*, a *qui tam* relator alleged that defendant retail drug suppliers violated the False Claims Act by charging dispensing fees to Medicaid that exceeded the dispensing fees charged to third party payors, in violation of a written agreement with the State of Alabama to provide prescriptions at an amount not in excess of the price charged to the "general public." 54 F. Supp. 2d at 1259-60. The contractual provision at issue was taken from federal and state regulations that refer to the "usual and customary charge to the general public." Defendants moved to dismiss the complaint on the grounds that the term "general public" referred to "the retail price or billed charges" and did not refer to "dispensing fees charged to other third-party payors." The court granted defendants' motion, finding: "there is no requirement in the federal

and state regulations, or the provider contract, that reimbursement from Medicaid not exceed reimbursement amounts provided by other third-party providers." *Id*. at 1260.

The terms "Direct Price" and "AWP" are more uncertain than the terms "miles" and "general public." This is particularly apparent where California is proffering a definition for purposes of its CFCA claim that deviates from its own statutory definitional framework. Because the terms "Direct Price" and "AWP" are at best uncertain and ambiguous, Plaintiffs cannot allege the requisite falsity needed to succeed on each of their claims. Accordingly, Counts I through V should be dismissed.

3. California's knowledge that AWP and Direct Price exceed actual cost defeats all counts in Plaintiffs' Amended Complaint.

California's knowledge that AWP and Direct Price often exceeded providers' "actual acquisition price" defeats all of Plaintiffs' CFCA claims. As discussed above, the regulatory and statutory history shows that California has long been aware that AWP and Direct Price exceed Medi-Cal providers' actual acquisition costs. This knowledge precludes a finding of falsity. California caselaw interpreting the CFCA makes it clear that there can be no CFCA liability where the government has knowledge of pertinent facts. *See Am. Contract Servs.*, 94 Cal. App. 4th at 864 (finding that "government's knowledge effectively negates the fraud or falsity required by the FCA") (citations omitted); *see also Boisjoly v. Morton Thiokol, Inc.*, 706 F. Supp. 795, 809 (D. Utah 1988) (finding government's knowledge of defect defeats False Claims Act violation).

In *American Contract Services*, the relator alleged that defendant submitted false claims in connection with a sole-source contract to supply California's Women and Infant Children ("WIC") program with 500,000 infant training cups. *See Am. Contract Servs.*, 94 Cal. App. 4th. at 856. According to the relator, the claims were "false" because California illegally entered into

a sole-source contract with defendant, disregarding state bidding requirements. *Id.* at 862-63. The California Attorney General moved to dismiss the complaint, contending that there cannot be a knowing presentation of a false claim where the government is aware of the facts surrounding the claim and approves it. *Id.* at 864. The motion was granted and the case was dismissed. On appeal, the court affirmed the dismissal of the case, holding that there can be no CFCA cause of action where the government's knowledge about the circumstances surrounding the claim negated the fraud or falsity required by the CFCA. *Id.*

Similarly, in *Boisjoly*, the qui tam plaintiff alleged that defendant submitted false claims in connection with the tragic Challenger launch. 706 F. Supp. at 798. Specifically, plaintiff alleged that defendant sold certain rocket parts to the government knowing that the parts were defective. *Id.* at 809. The district court dismissed the false claims act claim pursuant to Rule 12(b)(6) on the grounds that NASA knew of the defects at the time the false claims were allegedly made, thereby negating the required element of falsity. According to the *Boisjoly* court, "because FCA liability requires an element of fraud or falsity," there can be no liability "where the Government knew, or was in possession at the time of the claim, of the facts that make the claim false." *Id.* (citations omitted); *see also United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 544-45 (7th Cir. 1999) ("The government's knowledge [of an allegedly false claim] effectively negates the fraud or falsity required by the FCA."). In short, "[o]nly if the government gets something less than or different from that which it expected can it be said to have suffered the kind of injury necessary to invoke liability." *Id.*; *United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 988 (E.D. Wis. 1998) ("Since the crux of an FCA violation is intentionally deceiving the government, no violation exists where the government has not been deceived.").

It is undisputed that California knew that AWP and Direct Price often exceeded providers' acquisition costs. Accordingly, as in *American Contract Services* and *Boisjoly*, there can be no claim under the CFCA.

California's knowledge also serves to negate the intent necessary to support a false claims act claim. Defendants cannot have "knowingly" presented a fraudulent claim if the government knows and approves of the particulars of a claim for payment before that claim is presented. "In such a case the government's knowledge effectively negates the fraud or falsity required by the FCA." *FKW*, 189 F.3d at 545 (affirming district court's holding that government knowledge barred FCA claims); *see also Am. Contract Servs.*, 94 Cal. App. 4th at 779-80; *United States ex rel. Stone v. Rockwell Int'l Corp.*, 265 F.3d 1157, 1180 (10th Cir. 2001) (government knowledge relevant to defendants' intent under False Claims Act); *United States ex rel. Butler v. Hughes Helicopters*, 71 F.3d 321, 327 (9th Cir. 1995) (finding that when government representatives were made aware of alleged discrepancies, a contractor could not have "knowingly" submitted a false claim).

In light of the extensive public record showing that California knew that AWP and Direct Price often exceed "actual acquisition cost," Plaintiffs cannot possibly succeed in proving the scienter requirements for a violation of the CFCA.[12]

B. Counts I And IV Should Be Dismissed Because Defendants Did Not Present Or Cause To Be Presented A False Claim.

The first and fourth causes of action should also be dismissed because Defendants did not knowingly "present[] or cause[] to be presented . . . a false claim for payment or approval." Defendants did not submit or cause to be submitted any claims to Medi-Cal. Rather, as noted

[12] At the very least, Plaintiffs should not be able to recover damages after July 28, 1998 -- the date on which Ven-A-Care filed its complaint under seal. Plaintiffs should not be entitled to a windfall of civil penalties and damages by abusing the Attorney General's powers under the CFCA to keep this complaint under seal for over seven years, while at the same time continuing to pay providers' alleged "false" claims without objection.

and as Plaintiffs allege, providers submitted the claims. *See* Compl. ¶ 37. Nor does the Amended Complaint make sufficient allegations that Defendants "caused" the submission of any claims. There are no allegations that Defendants had any involvement whatsoever in the process by which providers submitted claims to Medi-Cal.

To allege sufficiently that Defendants "caused" the presentation of false claims under the CFCA, Plaintiffs must allege that Defendants had some degree of participation in the claims process. *See United States ex rel. Kinney v. Hennepin County Med. Ctr.*, No. Civ. A. 971680, 2001 U.S. Dist. LEXIS 25475 (D. Minn. Aug. 22, 2001); *see also United States ex rel. Shaver v. Lucas Western Corp.*, 237 F.3d 932, 934 (8th Cir. 2001) (knowledge that another is submitting false claims does not constitute "causation" under the FCA even where defendant knew that a false claim was going to be submitted as a result of its action).

In *Hennepin*, the court considered whether a defendant that provided emergency room physician staffing to hospitals violated the False Claims Act when its physicians signed Medicare and Medicaid claim forms certifying that the use of an ambulance was medically necessary, when it was not. *Hennepin*, 2001 U.S. Dist. LEXIS 25475, at *1-2. The forms were typically filled out by the hospital's paramedics, signed by defendant's physicians and ultimately forwarded to the hospital's billing department for coding and billing to Medicare or Medicaid. On these facts, the court held that defendant's certification did not cause the hospital to submit false or fraudulent claims because, among other things: (i) defendant had no control over the contents of the claims the hospital submitted to Medicare or Medicaid; (ii) defendant had no apparent right to review the claims being submitted to Medicare or Medicaid; and (iii) defendant did not instruct the hospital on what codes to use for billing to Medicare and Medicaid. Accordingly, the court dismissed the False Claims Act claims.

The facts alleged in this case closely resemble *Hennepin*. As in *Hennepin*, Plaintiffs' Amended Complaint does not allege that Defendants have control over the information contained in the claims or the ability to review the claims being submitted. And as discussed at detail above (*see supra* 24-25), California does not even allege that the claim forms themselves are false.

Accordingly, Defendants did not "cause" providers to submit false claims to Medi-Cal and Counts I and IV should be dismissed.

C. Count III Should Be Dismissed Because Defendants Are Not "Beneficiaries," Nor Did They "Discover" Any False Claims.

To state a claim under Cal. Gov't. Code Section 12651(a)(8) (Count III), Plaintiffs must allege that Defendants (1) are "beneficiaries" as that term is used in the CFCA; (2) subsequently discovered the falsity of a claim; and (3) failed to disclose the false claim to the state within a reasonable time after discovery. Plaintiffs cannot plead these elements because Defendants are not "beneficiaries" under the CFCA, and, in any event, Plaintiffs have not alleged that Defendants "discovered" any alleged false claims. Accordingly, Count III should be dismissed.

There is no case law discussing the definition of "beneficiary" as used in this provision of the CFCA, and the federal False Claims Act contains no corresponding cause of action. The most reasonable interpretation of "beneficiary" in the CFCA is the actual recipient of government funds (the Medi-Cal provider) or perhaps the person on whose behalf the payment was made (the Medi-Cal beneficiary). Under *any* reasonable interpretation, a "beneficiary" cannot be read as anyone who indirectly benefits from a government payment. That group of people would be far too broad; it would include, *inter alia*, spouses, shareholders, employees, children, and independent contractors of recipients of government money. The California legislature could not reasonably have intended to expose such an open-ended group of people to

CFCA liability. Defendants do not receive any Medi-Cal payments, nor are any claims submitted to Medi-Cal on their behalf. Accordingly, the term "beneficiaries" does not include Defendants.

Furthermore, Plaintiffs have failed to adequately allege that Defendants "discovered" any false claims. As Plaintiffs admit in the Amended Complaint, Defendants are removed from the claims process. *See* Compl. ¶ 37. Providers, not Defendants, submit the claims. Indeed, Defendants have no access to the claims to determine what the providers are submitting. Additionally, Defendants do not receive payment from Medi-Cal and have no access to Medi-Cal records to determine what amounts Medi-Cal paid providers. Moreover, the plain language of the statute requires Defendants to have known that the claims were false. Here, there's no allegation that Defendants knew or believed claims were "false." Plaintiffs' conclusory allegation that Defendants "[discovered] false claims," (Compl. ¶ 188) does not suffice, given that Defendants have no knowledge of the claims providers submit or Medi-Cal pays.

Because Plaintiffs cannot allege the requisite elements to state a violation of Cal. Gov't. Code Section 12651(a)(8), Count III should be dismissed.

D. Counts IV And V Should Be Dismissed Because Plaintiffs Do Not Allege Facts Sufficient To Constitute a Violation of California's Anti-Kickback Statute And, Alternatively, California's Anti-Kickback Statute Is Preempted By Federal Law.

As discussed above, Plaintiffs' fourth and fifth causes of action allege that Defendants violated the CFCA by violating California's anti-kickback statute (Cal. Wel. & Inst. Code Section 14107.2). Plaintiffs do not allege how a violation of the California anti-kickback statute by Defendants gives rise to a CFCA claim. Nor do Plaintiffs allege facts sufficient to constitute a violation under California's anti-kickback statute. Even if a violation of California's anti-

kickback statute has been alleged, however, the California statute is preempted by the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

1. Plaintiffs do not allege facts sufficient to constitute a violation of California's anti-kickback statute.

Plaintiff's fourth and fifth causes of action should be dismissed because they are premised upon a violation of California's anti-kickback statute - but the facts alleged, even if true, would not constitute such a violation.

In pertinent part, the statute provides that

> (b) Any person who *offers* or *pays* any *remuneration*, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind either:
>
> > (1) To refer any individual to a person for the furnishing or arranging for furnishing of any service or merchandise for which payment may be made, in whole or in part, under [the Medi-Cal program]; or
> >
> > (2) To purchase, lease, order, or arrange for or recommend the purchasing, leasing or ordering of any goods, facility, service or merchandise for which payment may be made in whole or in part under [the Medi-Cal program] is punishable….

CAL. WEL. & INST. CODE § 14107.2(b) (emphasis added).[13]

Under the plain language of the anti-kickback statute, the challenged conduct -- allegedly reporting inflated drug prices to pricing compendia -- does not constitute an "offer" or "payment" of remuneration to purchasers of pharmaceuticals from Defendants. According to the Ninth Circuit, in the anti-kickback context, an "offer" means "a representation expressing an ability and desire to pay a remuneration coupled with the intent to induce a desired action . . . ." *United States v. Duz-Mor Diagnostic Lab., Inc.*, 650 F.2d 223, 227 (9th Cir. 1981).

"Remuneration," in turn, is defined as "any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind." CAL. WEL. & INST. CODE § 14107.2(b).

Here, Plaintiffs have failed to assert that Defendants made an "offer" or manifested any representations of ability and/or desire to "pay" remuneration to providers in exchange for Medi-Cal business. Rather, Plaintiffs challenge Defendants' price reporting practices to pricing compendia. These reporting practices, however, are neither an offer nor a payment. Reporting practices do not constitute "remuneration." Certainly they are not kickbacks, bribes or rebates. Instead, Defendants' reporting practices are simply that -- list pricing parameters that are published in third-party compendia.

Even if Defendants' price reporting was a factor in determining how much Medi-Cal paid providers, and even if reimbursement levels influenced providers in deciding which manufacturers' drugs to purchase, it does not follow that Defendants violated the California anti-kickback statute. The California anti-kickback statute is violated only if one "pays" or "offers" remuneration. Plaintiffs do not allege that occurred here.

Because Plaintiffs have not alleged a violation of Cal. Wel. & Inst. Code Section 14107.2(b), Counts IV and V should be dismissed.

2. California's anti-kickback statute is pre-empted by the federal anti-kickback statute.

Counts IV and V also fail because California's anti-kickback statute is impliedly pre-empted by the federal anti-kickback statute. The federal anti-kickback statute contains a "knowing and willful" *mens rea* requirement not present in the California anti-kickback statute.

(continued…)

[13] CAL. WEL. & INST. CODE § 14107.2(a) makes it illegal for any person to solicit or receive the same remuneration stated in § 14107.2(b).

See Duz-Mor Diagnostic, 68 Cal. App. 4th at 669 (stating that the California anti-kickback statute differs from the federal anti-kickback statute, "most significantly" in that the federal statute includes a requirement that the conduct be knowing and willful). Additionally, the federal anti-kickback statute contains a safe harbor provision that is much broader than the safe harbor provision present in the corresponding California statute.[14]

Implied conflict preemption occurs, *inter alia*, "if state law interposes an obstacle to the achievement of Congress's discernable objectives." *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001) (internal citation omitted), *aff'd*, 538 U.S. 644 (2003). Because California's anti-kickback statute does not require the *mens rea* element of the federal anti-kickback statute, and because the California anti-kickback statute's safe-harbor provision is narrower than that of the federal version, California's anti-kickback statute prohibits certain discounts that are lawful under federal law and that would tend to reduce both federal and state Medicaid drug reimbursement costs. As this and related Medicaid litigation, as well as numerous legislation and regulations, demonstrate, reducing Medicaid reimbursement costs is a discernable objective of Congress. Forbidding such discounts, which in turn increases Medi-Cal reimbursement costs, is in contravention of congressional intent.

A Florida anti-kickback statute that, like California's, did not contain a "willfulness" requirement or safe harbor provision, was recently found unconstitutional because of an implied conflict preemption with the federal statute. *See Florida v. Harden*, 873 So. 2d 352, 355 (Fla. App. 2004) (affirming trial court's decision granting motion to dismiss). The Florida appellate court in *Harden* specifically found that the Florida anti-kickback statute "criminalizes certain

[14] This argument was previously raised in defendants' motion to dismiss in a related AWP case, *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314 (D. Mass. 2005), with respect to the Massachusetts anti-kickback statute. This Court deferred ruling on this particular argument because it was "raised late in the briefing, and the interpretation of the law is evolving." *Id.* at 325.

activity that is protected under the federal anti-kickback statute" and that "enforcement of the Florida anti-kickback statute would stand as an obstacle to the accomplishment and execution of the full purposes of objectives of Congress." *Id.* at 355. The California anti-kickback statute is similarly defective. Thus, there is no reason to reach a different result here and Counts IV and V should be dismissed.

E. Plaintiffs Fail To State A Claim For Drugs That Were Reimbursed On MAIC Or Any Basis Other Than AWP Or Direct Price.

Each of Plaintiffs' claims sounds in fraud, which (as Plaintiffs allege) requires a causal link between the alleged fraud (Defendants' allegedly false AWPs and Direct Prices) and California's injury (over-reimbursing providers for dispensing or administering Defendants' drugs). *See, e.g.*, Compl. ¶ 42 ("Defendants' inflation of their reported prices were misrepresentations which caused Medi-Cal to pay excessive reimbursements to providers who utilized Defendants' providers."). Plaintiffs' theory fails, however, with respect to drugs for which California did not pay reimbursement on the basis of AWP or Direct Price, but rather pursuant to Medi-Cal's other formulas for reimbursement, including MAIC, FAC (also known as "FUL"), or the amount charged by the provider.[15] *See* Compl. ¶ 27; CAL. WEL. & INST. CODE § 14105.45.

As explained above, *supra* 6 and 17, for certain multiple source drugs, California's Department of Health Services ("DHS") establishes its own maximum cost limits called "MAIC." As of 2002, California chose to set MAIC at the mean of the wholesale selling prices of drugs (generically equivalent to the particular innovator drug) derived from data provided by

[15] The flaws in Plaintiffs' theory as applied to drugs that are not reimbursed on the basis of AWP or Direct Price, such as multiple-source drugs, also highlight Plaintiffs' utter failure to plead with the particularity as required by Rule 9(b). Even though Plaintiffs admit that only in one of four possible scenarios does Medi-Cal reimburse on the basis of AWP or Direct Price, Plaintiffs lump all reimbursement together and plead no allegations stating that any particular drug and claim was reimbursed on an AWP or Direct Price-based formula, as opposed to the non-AWP and Direct Price formulas, which Medi-Cal also utilizes.

certain wholesale drug distributors. *See* CAL. WEL. & INST. CODE § 14105.45 (2003). California obtains the prices it uses to determine the MAIC directly from wholesalers -- not Defendants.[16]

In a complaint stretching over 70 pages (with 700 pages of exhibits) and 200 paragraphs, MAIC appears in only one paragraph. *See* Compl. ¶ 27. Plaintiffs do not allege that MAIC appears in any reporting service. *See* Compl. ¶ 32 (pleading that AWP, DP, and FUL -- and not MAIC -- are published in price reporting services). Nor do Plaintiffs delineate what drugs are reimbursed on MAIC, even though their exhibits acknowledge that MAIC is one basis for reimbursement. *See* Compl. Exs. A-R. Indeed, Plaintiffs never allege how Defendants are even connected to MAIC, a term that is entirely in California's discretion and control. Without any causal link to Defendants' conduct regarding AWP and Direct Price, Plaintiffs' allegations relating to drugs reimbursed based on MAIC must fail.

Medi-Cal's FAC reimbursement is taken from the federally-determined FUL for multisource products that is set by the Centers for Medicare and Medicaid Services ("CMS"), not Defendants. CMS determines the FUL for hundreds of products whenever commercially published compendia -- such as First DataBank, Medi-Span and the Red Book -- indicate that there are three suppliers of the same therapeutically equivalent drugs. *See* 42 C.F.R. §§ 447.331, 332 (2005); 52 Fed. Reg. 28,648 (July 31, 1987). The FUL is set by CMS at 150% of the single lowest price reported in the compendia, a reimbursement amount that is set by the federal government (not California) and has nothing to do with a generic drug's AWP or Direct Price. *See* 42 C.F.R. § 447.332.

[16] Prior to 2002, MAIC was determined under a different methodology involving certain manufacturer prices ("reference drug brands") selected by Medi-Cal. *See* CAL. WEL. & INST. CODE § 14105.45(b)(1)(2003). Again, Plaintiffs offer no allegations as to "reference drug brands" or how such terms may be connected to AWP or Direct Price. Without any allegations of a causal link with Defendants' conduct, Plaintiffs' claims based on MAIC prior to 2002 must also be dismissed.

As this Court has acknowledged in the class certification context, it is essential for Plaintiffs to show that generic drugs are reimbursed based on AWP when attempting to plead the type of fraud claims alleged here. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 91 (D. Mass. 2005) (ruling that, for third party payors in non-Medicare Part B context, "generics will be considered only to the extent the price in the contract between the TPP and physician is expressly predicated on AWP."). Here, Plaintiffs fail to do so. As a matter of law, there can be no link between Defendants' alleged misconduct (falsely inflated AWPs and Direct Prices) and California's claimed injury for any Medicaid reimbursement paid based on an MAIC, FUL or the provider's billed charge because such alternative formulas do not use Defendants' published AWP or Direct Price for a drug.[17]

Moreover, because both MAIC and FUL reimbursement apply a single reimbursement amount to any manufacturer's version of that drug, contrary to Plaintiffs' allegations, *e.g.* Compl. ¶ 1, no single defendant could "seize market share" by manipulating its AWP or Direct Price because any resulting effect (if there is one) on reimbursement would apply to every company's product, regardless of its published AWP or Direct Price. Accordingly, Plaintiffs' allegations relating to those drugs reimbursed based on MAIC and FUL must fail.

Accordingly, if a drug is reimbursed on a basis other than AWP or Direct Price, then claims as to those drugs should be dismissed.

CONCLUSION

For the reasons stated above, the Defendants respectfully request that Plaintiffs' First Amended Complaint-In-Intervention be dismissed in its entirety.

[17] Similarly, after September 30, 2002, there can be no liability for any reimbursement paid on the basis of "ASP" or "Selling Price" as well. Plaintiffs make no allegations regarding these terms, much less how Defendants' conduct regarding AWP or Direct Price affected ASP or Selling Price.

Dated: January 17, 2006

SUBMITTED ON BEHALF OF ALL LISTED DEFENDANTS BY:

/s/ Toni-Ann Citera

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Counsel for Defendant Abbott Laboratories Inc. and signing on behalf of all listed Defendants

Abbott Laboratories Inc.
Armour Pharmaceutical Co.
Aventis Pharmaceuticals Inc.
B. Braun Medical Inc.
Baxter Healthcare Corp.
Ben Venue Laboratories, Inc.
Boehringer Ingelheim Corp.
Bristol-Myers Squibb Company
Dey, Inc.
Dey, L.P.
Immunex Corp.
Mylan Laboratories Inc.
Mylan Pharmaceuticals Inc.
Roxane Laboratories, Inc.
Sandoz Inc.
Schering-Plough Corp.
Warrick Pharmaceuticals Corp.
ZLB Behring LLC (f/k/a Aventis Behring LLC)

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 17, 2006, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Tara A. Fumerton
Tara A. Fumerton